Remarks

Claims 1-24, and 32-39 are presented for the Examiner's review and consideration. In this response, claims 1, 13, 21-22, and 32 are amended, and claim 39 is added. Applicant believes the accompanying remarks herein serve to clarify the present invention and are independent of patentability.

§102 Rejection

Claims 1-24 and 32-38 were rejected under 35 U.S.C. §102(e) as being anticipated by Badorf et al. (6,214,051) ("Badorf"). For reasons set forth below, Applicant respectfully submits that this rejection should be withdrawn.

Badorf

Badorf discloses a knee-joint endoprosthesis includes a metallic femoral part anchored in the femur that articulates with a tibial part anchored in the tibia bone, the articulating surface of the femoral part being a ceramic structural member that is connected to the femoral part in a mechanically stable manner. (Abstract). The attachment of the ceramic structural member to the femoral part, can be accomplished by using a conical clamping device, by use of a fixing screw, by shrinking, soldering or welding it on, or by vapor deposition or spray application. (Id).

In one embodiment according to the invention the ceramic structural member is anchored on the femoral part by means of a conical clamping device. (Col. 1, lns. 19-21). In an alternative embodiment the structural member is anchored on the femoral part by means of at least one fixing screw. A conical clamping device would be dispensed with in this case. (Col. 1, lns. 34-37). In another alternative embodiment the ceramic structural member is connected to the femoral part in a non-detachable manner by shrinking, soldering or welding. Soldering also includes active soldering. (Col. 1, lns. 41-44).

FIG. 2 shows a lateral section through a femoral part 2 with, likewise, a structural member 3 that is mounted with the aid of a conical clamping device 4. (Col. 2, lns. 35-37). The conical clamping device 4 in this case, as distinct from the embodiment of FIG. 1, is disposed only above what is the loading zone when the knee is extended. (Id).

Thus Badorf is directed to mounting a ceramic articulating surface on a metal implant anchored to the femur. Badorf discloses different clamping locations for the ceramic surface, one where clamping is performed in a particular location relative to an extended leg.

Present Invention

A general discussion of the present invention has been provided in a Response to a previous Office Action, and in the interests of brevity, is incorporated herein by reference. Support for the present invention as claimed herein may be found in the specification at least in the following locations.

Other Joints, More than Two Portions

The implant 290 is connected with the femur 126. However, it is contemplated that a tibial implant could be formed as a plurality of separate portions which are interconnected when they are in the knee portion 76 of the patient's leg 70. (¶[0370]). It should be understood that the implant 290 could be formed of more than two portions. (Id). For example the implant could be formed with four separate portions which are interconnected in the patient's body. (Id). Although the implant 290 is to be used in a knee portion of a patient's body, it is contemplated that implants used at other portions of a patient's body could be interconnected in the patient's body. (Id).

Multi Part Implant Passed Through Smaller Incision

In contrast, in the present invention, in order to enable surgery on a knee portion 76 of a patient's leg 70 to be conducted through an incision 114 of relatively small size, the implant may advantageously be formed in two or more portions (FIG. 40). (¶[0360]). The portions of the implant are sequentially moved through the incision 114 into engagement with the distal end portion 124 of the femur 126 and/or the proximal end portion 212 of the tibia 214. (Id). It is believed that having the implant formed as two or more portions will facilitate movement of the implant through the cannula 564 (FIG. 39). (Id).

Engagement with Bone, Then Interconnected

As the portions of the implant are sequentially moved through the incision 114, they are positioned in engagement with one or more of the bones, that is, the femur 126 and/or the tibia

214 in the leg 70 of a patient. (¶[0361]). After the plurality of portions of the implant have been moved through the incision 114 and positioned in engagement with the femur 126 and/or tibia 214, the portions of the implant are interconnected to form a unitary implant. (Id). If desired, the portions of the implant are moved through the incision 114 and interconnected while the leg of the patient is in the position illustrated in FIGS. 2, 3 and 25. (Id).

Polymeric Bonding

The specific implant 290 illustrated in FIG. 40 has portions formed of a polymeric material which may be either a polymer or a co-polymer. (¶[0365]). The material of the two portions 572 and 574 of the implant 290 are heated at the joint 576 while the two portions of the implant are disposed in the patient's body in engagement with the femur 126. (Id). As this occurs, the material forming the two portions 572 and 574 of the implant 290 is heated to a temperature within its transition temperature range and becomes tacky without changing its overall configuration. (Id). The two portions 572 and 574 of the implant 290 may be heated by the direct or indirect application of heat. (Id). The indirect application of heat may include applying ultrasonic energy to the implant. (Id).

The heated material of the two portions 572 and 574 of the implant 290 are then pressed together at the joint 576 to form a bond between the two portions of the implant. (¶[0366]). As this occurs, there is a fusing of the material of the portion 572 of the implant 290 with the material 574 of the implant. (Id). This fusing together of the two portions 572 and 574 occur in the patient's body and results in the formation of a one-piece unitary implant 290. (Id).

Rather than being formed of a polymeric material, it is contemplated that the two portions 572 and 574 of the implant could be formed of metal and have a polymeric layer on a side of the metal toward the femur 126. (¶[0367]). This would result in the layer of polymeric material being disposed in engagement with the distal end portion 124 of the femur 126 and the metal forming the femoral component 290 facing toward the tibia 214 for engagement with the tibial bearing insert 294 (FIG. 32). (Id). With such a construction, the application of energy to the two portions 572 and 574 of the implant would result in a heating of the layer of polymeric material on the inside of the layer of metal. (Id). The heated polymeric materials on the two portions 572 and 574 bond together at the joint 576 in a manner previously described. (Id).

Suspended Leg

If leg 70 is positioned as shown in FIGS. 2 and 3, positioning of the femoral alignment guide 134 and anterior resection guide 138 on the distal end portion 124 of the femur 126 is facilitated by distracting the knee joint under the influence of the weight of the lower portion 68 of the patient's leg and the foot 74. (¶[0184]).

By making the incision 114 with the leg in a flexed condition (FIGS. 2, 3, and 6) and operating on the leg 70 with the leg in a flexed condition, the overall length of the incision can be reduced from the length of incisions which have previously been made in the leg when it is in the extended condition. (¶[0162]).

Lateral and Medial Portions

FIG. 87 shows one manner of coupling the sections. (¶[0655]). A tongue 1238 located on one section (shown as anterior femoral section 1234) mates with a groove 1240 on an adjacent section (shown as posterior femoral section 1236). (Id). The mating results in substantially smooth condyle surfaces 1228 so as to minimize the potential for generation of wear debris. (Id).

Figures 40 and 87 illustrate separate medial and lateral condylar sections.

As such, the present invention discloses passing multiple implant portions through a reduced size incision in a minimally invasive surgical procedure. The implant may be positioned against the bone and connected along a mating polymeric surface, or connected inside the body, and then placed against the bone. One surface of each portion contacts the bone, and abutting side surfaces are affixed. Separate medial and lateral joint sections may be affixed to form a unitary implant.

In contrast, Badorf does not disclose or suggest an abutting surface of polymeric material. Badorf is directed only to a ceramic articulating surface bonded to a metallic base. The rejection does not provide a reference or citation for a polymeric element.

Badorf does not suggest or disclose implanting an implant portion when a leg is suspended.

Further, Badorf does not disclose or suggest a plurality of implant portions affixable to a femoral joint member. Rather, only a single portion is affixed to a femoral joint member, and a ceramic element is affixed to the single portion.

Claim 1 recites, *inter alia*, a plurality of separate implant portions each having an abutting side surface, the side surface including polymeric material interconnectable and affixable together with at least one side surface of a mating implant portion, after said implant portions are passed separately through the skin, by the application of an energy source applied to mating polymeric material of said abutting side surfaces, to form a unitary implant having an articulating surface.

An advantage of the present invention is that a smaller opening may be made in skin, thus reducing trauma, bleeding, and tissue damage, and speeding recovery from surgery. There is no disclosure or suggestion in Badorf of passing a substantially smaller implant through the skin, and thus this advantage is not realized in Badorf. The subsequent addition of ceramic surfaces such as are shown and described in Badorf would not substantially reduce the size of the incision, since the total femoral replacement shown in Badorf is not reduced in size, and would require an incision size far greater than that which would be required by the ceramic element alone.

Claim 1 further recites that the implant portions are passable through an opening in skin that is substantially less wide than the formed unitary implant.

In Badorf, a large single implant covering the entire distal portion of the femur is disclosed. Thus, the implant must be large enough to contact and cover both the medial and lateral sides of the resected femur bone. The present invention provides separate medial and lateral sides which contact the bone, and thus enables a far smaller implant portion to be passed through the skin.

Claim 13 recites, *inter alia*, a plurality of separate implant portions each having a bone contacting surface, and at least one abutting side surface, the side surface including polymeric material interconnectable and affixable together with at least one side surface of a mating implant portion, after said implant portions are passed separately through the skin to form a unitary implant, one of said separate implant portions replacing at least a portion of a medial side of the body joint, and another of said separate implant portions replacing at least a portion of a lateral side of the body joint, thereby forming an articulating surface comprising at least separate medial and lateral implant portions.

Claim 22 recites, *inter alia*, sequentially positioning the plurality of separate implant portions on the prepared bone of the joint member.

Claim 32 recites, *inter alia,* forming a plurality of separate joint replacement portions, each having a bone contacting surface and an abutting surface, at least the abutting surface including polymeric material; and, providing said plurality of separate implant portions, to be passed separately into the body, wherein said abutting surface of at least two of said separate implant portions are abutted and connected together in the body through the application of ultrasonic energy.

Applicant notes that the use of ultrasonic energy, as claimed in claim 32, is not disclosed or suggested in Badorf.

Badorf discloses only methods of attaching ceramic to metal, including vapor deposition, spray application, soldering, shrinking, welding, active welding, screws, and springs. In contrast, the present invention discloses bonding of polymeric side surfaces (Fig's. 40, 87, and as cited above) using heat. Advantages of bonding polymeric surfaces as compared to Badorf include an avoidance of additional chemicals or components, avoidance of bioreactive components, low heat requirements thus avoiding necrosis of adjacent tissue, and the generation of reliable and consistent bonds.

Claim 21 recites, *inter alia*, first and second implant portions passed separately through an opening in the skin of the body, each having a bone contacting surface, and at least one abutting mateable side surface including polymeric material, the side surfaces bondable together within the body by the application of an energy source operative to produce heat within said polymeric material to form a unitary implant affixable to a femoral joint member of a knee joint.

Accordingly, Applicant respectfully submits that independent claims 1, 13, 21-22, and 32 are patentable over Badorf. As claims 2-12 and 38 depend from claim 1; 14-20 from claim 13; 23-24 from claim 22; and 33-37 from claim 32, these dependent claims necessarily include all the elements of their base claim. Accordingly, Applicant respectfully submits that the dependent claims are allowable over Badorf for at least the same reasons.

In light of the foregoing, Applicant requests reconsideration and withdrawal of the section 102 rejection.

New Claim 39

Claim 39 has been added, dependent from claim 21. As stated above, Applicant submits that claim 21 is patentable over Badorf. As claim 39 necessarily includes all the elements of its base claim, Applicant respectfully submits that the dependent claim is allowable over Badorf for at least the same reasons. Further, as discussed above, Badorf does not disclose implanting an implant portion while the lower portion of the leg is suspended.

Conclusion

In light of the foregoing remarks, this application is now in condition for allowance and early passage of this case to issue is respectfully requested.

If any questions remain regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

A fee of $25 for an additional dependent claim, and $120 for a one month extension are believed to be due. However, please charge any other required fee (or credit overpayments) to the Deposit Account of the undersigned, Account No. 503410 (Docket No. 780-A03-012A).

Respectfully submitted,

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